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| 09/883,112 | 06/14/2001 | Frederick F. Becker | UTXC:626US/MCB | 7970 |

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| EXAMINER | |
|---|---|
| DO, PENSEE T | |

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| 1641 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/883,112 | BECKER ET AL. | |
| | Examiner | Art Unit | |
| | Pensee T. Do | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-18,24-31,33-39 and 41* is/are pending in the application.

4a) Of the above claim(s) *1-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-31,33-39 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18, 24-31, 33-39, 41* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Amendment Entry & Claims Status*

The amendment filed on February 14, 2007 has been acknowledged and entered.

Claims 1-18 are withdrawn from further consideration.

Claims 24-31, 33-39 and 41 are being examined.

### *Withdrawn Rejection(s)*

Rejections under 103 in the previous office action are withdrawn herein.

### *New Grounds of Rejection*

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-31, 33-39, and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The present specification fails to describe or provide support for the newly incorporated limitations, i.e. providing the complex to a field flow fractionation chamber; and providing a fluid flow in the fluid fractionation chamber.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-31, 33-39, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33, 36 and 41, "the fluid fractionation chamber" lacks antecedent basis.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33, 34, 36-39, 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewart et al. (US 5,922,537) in view of Becker et al. (US 5,888,370).

Ewart teaches an assay method, sandwich, indirect, competitive or direct assay, using reporter particles such as dielectric particles (see col. 4, lines 6-14). The core particles can be made from a wide variety of inorganic materials including metals such as gold, silver, platinum (see col. 5, lines 17-26). The particle core can be encapsulated in a polymer such as polystyrene (see col. 7, lines 20-30). The dielectric particles can be engineered to have one or more dielectric properties or paramagnetic properties and phosphorescent properties (see col. 11, lines 7-13). In the assay, the target analyte is contacted with the reporter particles linked to a ***recognition molecule*** (linking element) that specifically binds the target analyte. (see col. 4, lines 53-65). The dielectric particles/labels contributes the dominant dielectric constant (second dielectric property)

in the complex analyte-recognition molecule-dielectric label (see col. 14, lines 33-38). The dielectric property of an unbound dielectric label is the first dielectric property. The recognition molecule/linking element comprises of antibody, hormone, antigen, etc. (see col. 7, lines 54-65). The sample is bodily fluid such as blood (see col. 4, lines 49-51). Ewart also teaches that the dielectric particles/labels move in an electrophoretic field when being applied in a separation method (see col. 11, lines 27-31). Trapping is performed when the particles captures the analyte. Sorting is the same as separating and purification. Ewart teaches detection is by measuring the capacitance change due to a change in effective dielectric constant and effective thickness of the dielectric layer upon complex formation between the analyte and the recognition molecule. (see col. 13, lines 1-5). Thus, it is inherent that a capacitance measurement is performed before the formation of the complex (analyte and recognition molecule). Thus, measuring the capacitance change is the same as distinguishing the first and second dielectric properties. Ewart teaches the sample is water. (see col. 13, line 7).

However, Ewart fails to teach detection using dielectrophoresis field flow fractionation separation or responses to an AC electrical field; and providing the complex to a field flow fractionation chamber; providing fluid flow in the fluid fractionation chamber.

Becker teaches a method and apparatus for separation characterization and manipulation of mater using dielectric and conductive properties of particulate matter and solubilized matter with the properties of the suspending and transporting medium to discriminate and separate such matter. The apparatus comprises a chamber with an

inlet port and outlet port. (see col. 3, lines 25-48) and at least one electrode electrically connected to an electrical conductor. (see col. 3, lines 49-55). The electrodes are energized by at least one electrical signal from the electrical signal generator to create a spatial inhomogeneous alternating electric field, which may cause a Dielectrophoresis force on a particulate matter and solubilized matter having components normal to the fluid (fluid flow) traveling through the chamber (fractionation chamber). (see col. 4, lines 41-55). The method uses dielectrophoresis and field flow fractionation as follows: the matter to be separated/detected is introduced into the chamber. Next a transport fluid (fluid flow) is introduced into the chamber. The effect of this fluid in the chamber causes a fluid flow in the chamber at a speed according to the velocity profile within the chamber. At least one electrical signal is applied to the electrode at different phases. These energized electrodes thereby create a traveling electric field, which may also be spatially inhomogeneous, within the chamber. The field causes a dielectrophoresis force on the matter (to be separated/detected) to be displaced to a position within the transport fluid to flow. (see col. 12, line 64-col. 13, line 17).

It would have been obvious to one of ordinary skills in the art to use the apparatus disclosed by Becker in the method of Ewart to detect complexes of analyte and recognition molecules using their dielectric properties because Becker combines the use of frequency dependent dielectric and conductive properties of particles with the properties of the suspending and transporting medium and Ewart teaches using dielectric and conductive particles in assay. Thus, combining these references would

be an advantage for highly discriminate separation and sensitive manipulation of the complex from the other particulate matter in the sample with different dielectric properties.

Claims 24-31, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewart in view of Becker as applied to claims 33 and 36 above, and further in view of Vo-Dinh (6,219,137).

Ewart and Becker have been discussed above.

However, Ewart and Becker fail to teach that the insulating layer (polymeric coating) comprises one or more self-assembled monolayer layers.

Vo-Dinh teaches a nanoprobe comprising a metallic system, which provides the Surface Enhanced Raman Spectroscopy (SERS) effect, and a chemical or biological system, which provides selective binding within a cell. The nanoprobe has a metallic core, which may be magnetic or electrically charged materials. For example, the core may be solely metallic material or a non-metallic material with a metallic coating. The core has an external coating formed of a polymer, a biological material (antibody, enzyme, or DNA) or biometric material. A nanoprobe has specific receptors. Multiple nanoprobes can be used in high throughput screening for drug detection or medical diagnostics. (see col. 2, lines 43-63). The metallic core or surface can be coated with a monolayer of thiols for binding DNA oligonucleotides or peptide nucleic acids because thiols are known to strongly chemisorb to gold and silver surfaces to form monolayers that possess supra molecular properties. (see col. 5, lines 37-46).

It would have been obvious to one of ordinary skills in the art to modify the particles of Ewart for use in combination with the apparatus of Becker so that they comprise a coating of thiols for attaching DNA as taught by Vo-Dinh since theses references teach coating metallic particle/core with a thin film or monolayer, and attaching DNA to the microparticles. Since the specification teaches that the self-assembled monolayer is thiols, and Vo-Dinh teaches thiols, such thiols in Vo-Dinh would self-assemble as a monolayer on gold/metallic surface.

***Response to Arguments***

Applicant's arguments with respect to claims 24-31, 33-39 and 41 have been considered but are moot in view of the new ground(s) of rejection.

Regarding claim 41, it should have been rejected along with claims 36-39 in the previous office action since it has all the limitations of claims 33 and 36 which were rejected. However, this action is made non-final because this claim is now rejected under new grounds of rejection.

Regarding the restriction/election requirement, the office action summary indicates that claims 1-18, 24-31, 33-39 and 41 are subjected to a restriction/election requirement because claims 1-18 were restricted. Thus, all the pending claims have such status. It would be removed if claims 1-18 were canceled.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
October 11, 2007

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